ATTACHMENT A

DIAGNOSTIC TESTING ALGORITHM #1

Diagnostic Test for Hepatitis C Virus (HCV) Requested
Specimens collected for:
1. Enzyme immunoassay (EIA)
2. Recombinant immunoblot assay (RIBA)

EIA signal to cutoff ratio* is *positive*, but < 3

EIA signal to cutoff ratio* ≥ 3.8

RIBA

—

+ or indeterminant

HCV antibody test is positive
Clinician receives these results:
1. EIA
2. RIBA if EIA signal to cutoff ratio* < 3.8

HCV antibody test is negative

Note: False negative antibody test results are possible in immunosuppressed patients. If HCV infection is strongly suspected in such a patient and the antibody test is negative, a qualitative HCV RNA should be done.

Further laboratory tests to consider:
1. HCV RNA
2. HCV genotype
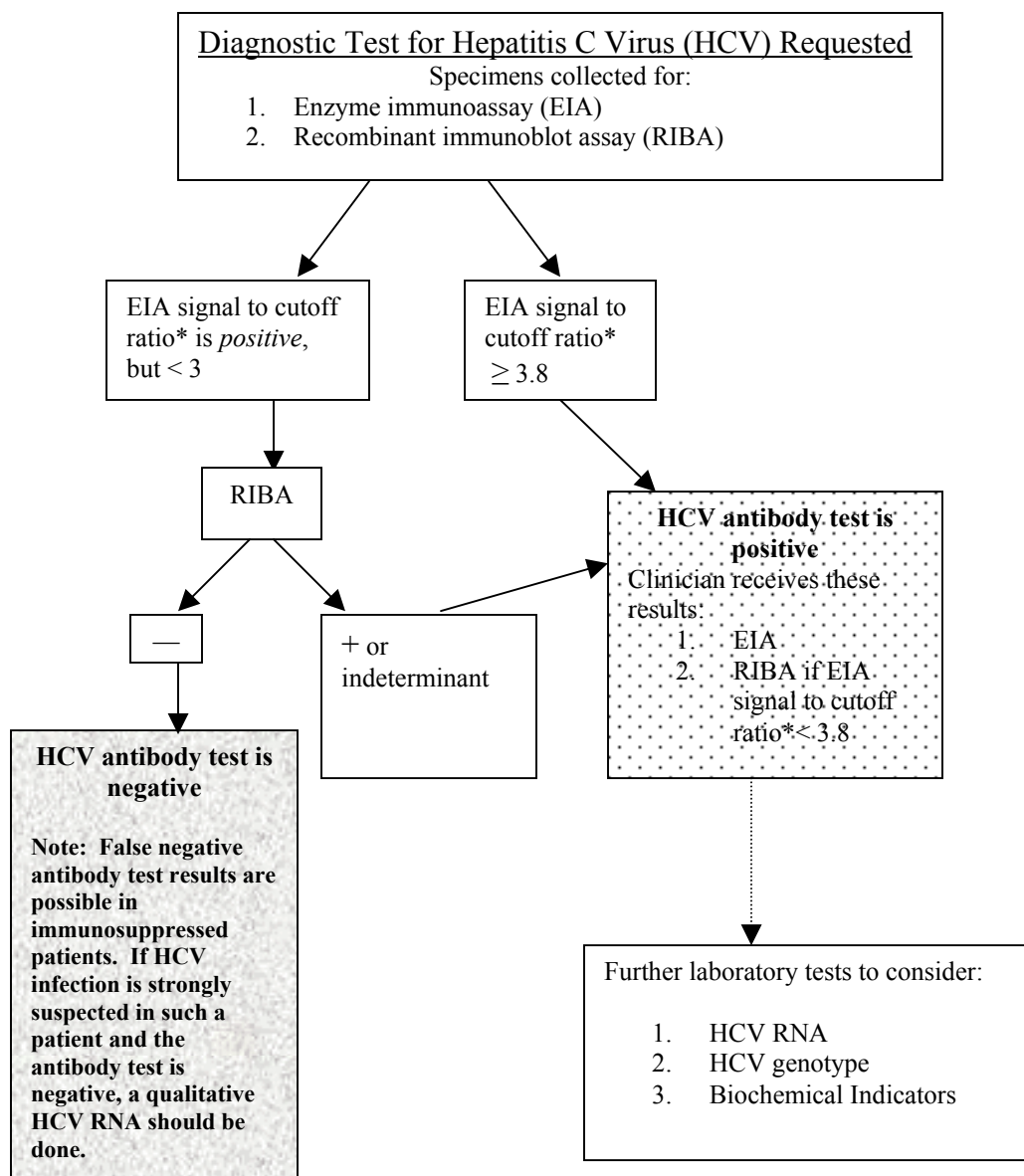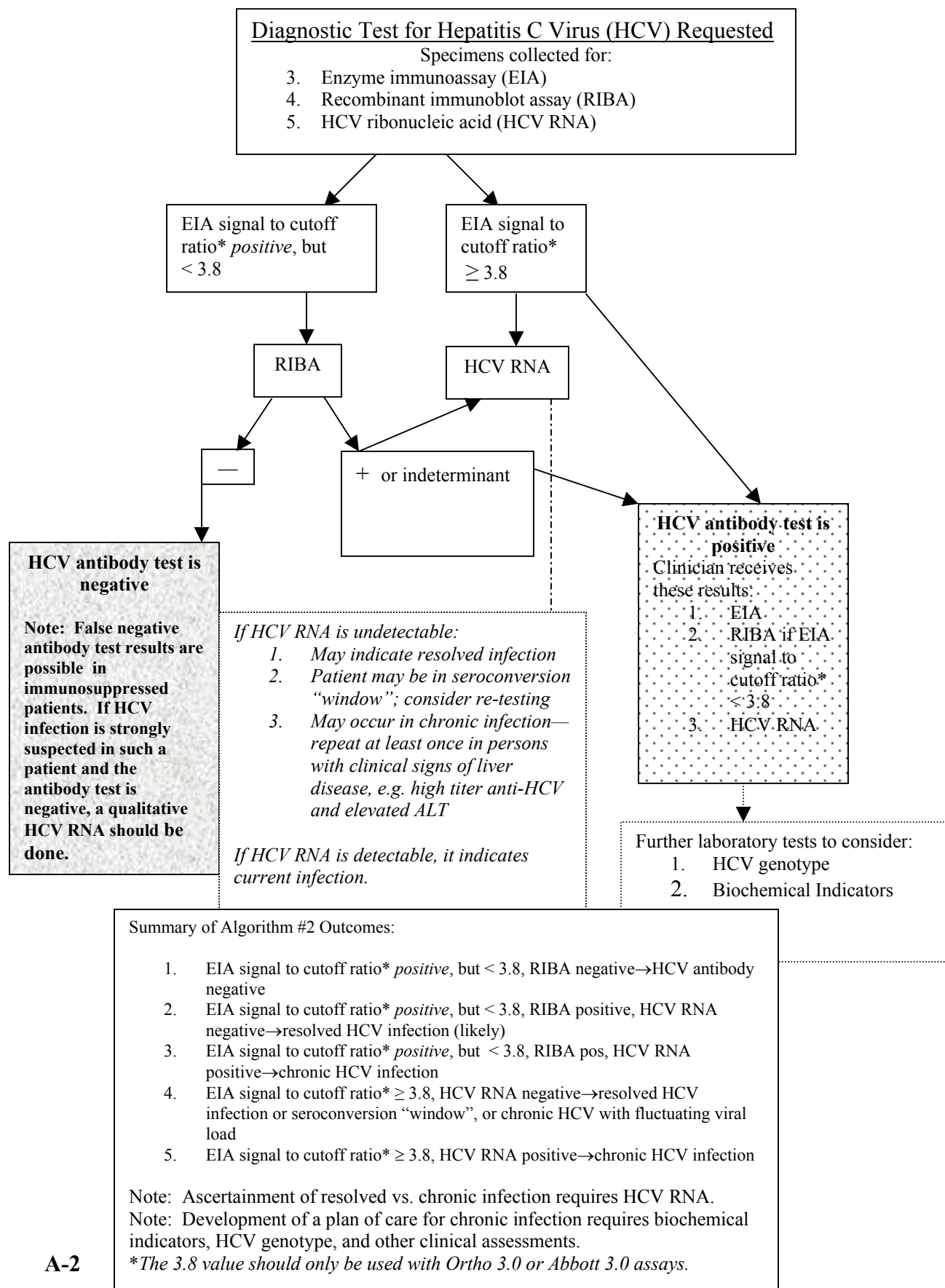3. Biochemical Indicators

Summary of Algorithm #1 Outcomes:

1. EIA signal to cutoff ratio* *positive*, but < 3.8, RIBA negative→HCV antibody negative
2. EIA signal to cutoff ratio* *positive* , but < 3.8, RIBA positive→HCV antibody positive
3. EIA signal to cutoff ratio* ≥ 3.8→HCV antibody positive

Note: Ascertainment of resolved vs. chronic infection requires HCV RNA.
Note: Development of a plan of care for chronic infection requires biochemical indicators, HCV genotype, and other clinical assessments.

The 3.8 value should only be used with Ortho 3.0 or Abbott 3.0 assays.

DIAGNOSTIC TESTING ALGORITHM #2

Diagnostic Test for Hepatitis C Virus (HCV) Requested
Specimens collected for:
3. Enzyme immunoassay (EIA)
4. Recombinant immunoblot assay (RIBA)
5. HCV ribonucleic acid (HCV RNA)

EIA signal to cutoff ratio* *positive*, but < 3.8

EIA signal to cutoff ratio* ≥ 3.8

RIBA

HCV RNA

−

+ or indeterminant

HCV antibody test is negative

Note: False negative antibody test results are possible in immunosuppressed patients. If HCV infection is strongly suspected in such a patient and the antibody test is negative, a qualitative HCV RNA should be done.

If HCV RNA is undetectable:
1. *May indicate resolved infection*
2. *Patient may be in seroconversion "window"; consider re-testing*
3. *May occur in chronic infection— repeat at least once in persons with clinical signs of liver disease, e.g. high titer anti-HCV and elevated ALT*

If HCV RNA is detectable, it indicates current infection.

HCV antibody test is positive
Clinician receives these results:
1. EIA
2. RIBA if EIA signal to cutoff ratio* < 3.8
3. HCV RNA

Further laboratory tests to consider:
1. HCV genotype
2. Biochemical Indicators

Summary of Algorithm #2 Outcomes:

1. EIA signal to cutoff ratio* *positive*, but < 3.8, RIBA negative→HCV antibody negative
2. EIA signal to cutoff ratio* *positive*, but < 3.8, RIBA positive, HCV RNA negative→resolved HCV infection (likely)
3. EIA signal to cutoff ratio* *positive*, but < 3.8, RIBA pos, HCV RNA positive→chronic HCV infection
4. EIA signal to cutoff ratio* ≥ 3.8, HCV RNA negative→resolved HCV infection or seroconversion "window", or chronic HCV with fluctuating viral load
5. EIA signal to cutoff ratio* ≥ 3.8, HCV RNA positive→chronic HCV infection

Note: Ascertainment of resolved vs. chronic infection requires HCV RNA.
Note: Development of a plan of care for chronic infection requires biochemical indicators, HCV genotype, and other clinical assessments.

A-2 *The 3.8 value should only be used with Ortho 3.0 or Abbott 3.0 assays.*

DIAGNOSTIC TESTING ALGORITHM #3

Diagnostic Test for Hepatitis C Virus (HCV) Requested
Specimens collected for:
1. Enzyme immunoassay (EIA)
2. Recombinant immunoblot assay (RIBA)
3. HCV ribonucleic acid (HCV RNA)

EIA negative

EIA positive
(any optical density
[O.D.])

HCV RNA

undetectable

detectable

RIBA

_   +

HCV antibody test is positive
Clinician receives these results:
1. EIA
2. HCV RNA, if EIA positive
3. RIBA, if HCV RNA undetectable

Further laboratory tests to consider:
1. HCV genotype
2. Biochemical Indicators

HCV antibody test is negative

Note: False negative antibody test results are possible in immunosuppressed patients. If HCV infection is strongly suspected in such a patient and the antibody test is negative, a qualitative HCV RNA should be done.

If HCV RNA is undetectable:
1. *May indicate resolved infection*
2. *Patient may be in seroconversion "window"; consider re-testing*
3. *May occur in chronic infection—repeat at least once in persons with clinical signs of liver disease, e.g. high titer anti-HCV and elevated ALT*

If HCV RNA is detectable, it indicates current infection.

Summary of Algorithm #3 Outcomes:

1. EIA negative→HCV antibody negative
2. EIA positive at any O.D, HCV RNA undetectable, RIBA negative→false positive EIA
3. EIA positive at any O.D, HCV RNA undetectable, RIBA positive→ resolved HCV infection or seroconversion "window", or chronic HCV w/fluctuating viral load
4. EIA positive at any O.D, HCV RNA detectable→chronic HCV infection

Note: Ascertainment of resolved vs. chronic infection requires HCV RNA.
Note: Development of a plan of care for chronic infection requires biochemical indicators, HCV genotype, and other clinical assessments.